防疫用品证书真伪辨别共性问题（第二版）

一、出口美国企业 FDA 注册情况辨别

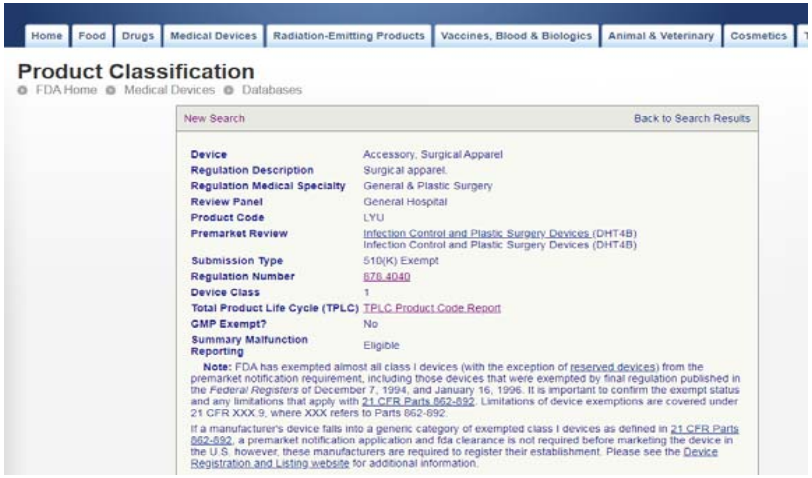
根据企业提供的注册信息（可能是中介机构提供的证明文件），首先点击：

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm（在“Owner/OperatorName”栏输入企业名称或“owner/operater Number”栏输入企业号码查询，输入搜索后出来页面如下图所示，表格中有两行，第一行是企业信息，第二行是产品信息）。

注：网站上能查到不代表 FDA 已批准。

然后点击上图所示的产品信息（点击后界面如下图所示）：

进一步点击具体的 product code 代码（如图中 LYU），点击后如下图：



在上图“submission type”项确认是否是 510（k）豁免（如

图显示“510（K）Exempt（510（K）豁免）”）。注：“LYU”类别实际仅是“外科服类的附件”，不包括口罩，但该企业注册产品显示是“Disposible medical Mask”（一次性医用口罩），走此类别注册显然是不正确的，存在很高风险。

需重点关注：**现场需要通过核实“DMR（产品主文档）、测试报告、美国 FDA 备案信息、产品标签和说明书等”确认企业实际生产出口的产品与在 FDA 网站注册的类别是否一致。**目前存在大量实际产品与注册类别不一致情况，特别对于不需 510（K）仅在 FDA 网站注册即出口的企业，FDA 不对企业和产品注册信息审查，注册错误造成的风险企业自己承担，一旦类别报错，在产品销往美国后即使当时没查到，未来也可能面临很高的法律诉讼风险。如很多企业将一次性外科口罩放在“LYU”类别中注册，但该类别实际仅是“外科服类的附件”，不包括口罩。

产品分类情况可通过以下网址查询（可提供给企业针对对应的法规进行研究）：

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

二、出口欧盟 CE 认证和自我符合性声明的辨别

（一）是否需要公告机构认证的辨别

确认实际产品属于哪种类型，个人防护性口罩（EN149）和医用灭菌口罩均需要第三方公告机构介入发证。医用非灭菌口罩由企业做自我声明，欧盟代表帮助企业在欧盟成员国进行产品注册（备案）。

（二）公告机构辨别

根据总局发的公告机构清单和公告机构号核实（已做两张长图，可放手机中随身携带使用）。

（三）国内具备欧盟公告机构口罩等业务资质的认证机构（9 家）证书真伪核实方式

1. 南德认证检测（中国）有限公司（TÜV SÜD Product Service GmbH Zertifizierstellen（NB0123））
https://www.tuvsud.com/en/services/product-certification/ps-cert

2. BSI 英标

https://verifeyedirectory.bsigroup.com/Results（点击验证）进行验证或致电垂询 BSI：400-005-0046

3. 莱茵检测认证服务（中国）有限公司

https://www.certipedia.com/?locale=en

4. 上海天祥质量技术服务有限公司，验证邮箱：Certificate.validation@intertek.com

5. 安诺尔认证服务(上海)有限公司

注：对于没有查询证书真伪网址的公告机构，可依据所持证书上的邮箱地址发送证书编号和该证书复印件到该邮箱进行查询。

（四）CE 认证证书真伪辨别

CE 认证证书必须由欧盟公告的有该产品类型资质的合法机构颁发。即：必须是欧盟医疗器械指令（MDD 或 MDR）或个人防护设备法规（PPE）的公告机构，且医疗器械认证资质与个人防护产品认证资质是分开的。各个公告机构的资质范围可通过以下网站查询：

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main

不具备以上条件的证书都视为无效证书。不能拿其他审查报告等文件充当 CE 证书。对于产品类别属于**自我声明贴 CE 标的产品**，企业需要准备技术文档和相关标准的测试报告、任命欧盟代表，并且在成员国完成注册，产品和/或标签才能贴上 CE 标记，即可在欧盟清关。**注意：**任何证书都不能带有 CE 标志. CE 标志只能贴附到企业的标签和说明书里。没有在国内（大陆）设置分支机构的欧盟医疗器械和个人防护设备的公告机构，CE 证书可关注证书上机构地址辨别。

三、无效证书的示例

（一）超范围发放的 CE 证书

1. ECM 公告范围不包括个人防护设备，而发放的个人防护口罩证书，属于超范围发证，证书无效。

2. ICR 是欧盟在电气电子设备领域的公告机构，在医疗器械和个人防护设备领域无相应资质，属于超范围发证，证书无效。

International Certification Registrar International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska M4500211 CE

Name and address of certificate owner:	Jiangsu Yunuokang Trading Co. , Ltd. 70 Yangshan road, Xuzhou, Jiangsu Province, China.
Name and address of manufacturer:	Jiangsu Yunuokang Trading Co. , Ltd. 70 Yangshan road, Xuzhou, Jiangsu Province, China.
Product name:	Disposable mask
Product types:	A8
Product trademark:	N/A

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by Shenzhen Beyon Certification Co. ,Ltd.

No. of test reports:	**LT200327121**
Certificate issue date:	25.03.2020
Expiration date:	24.03.2025

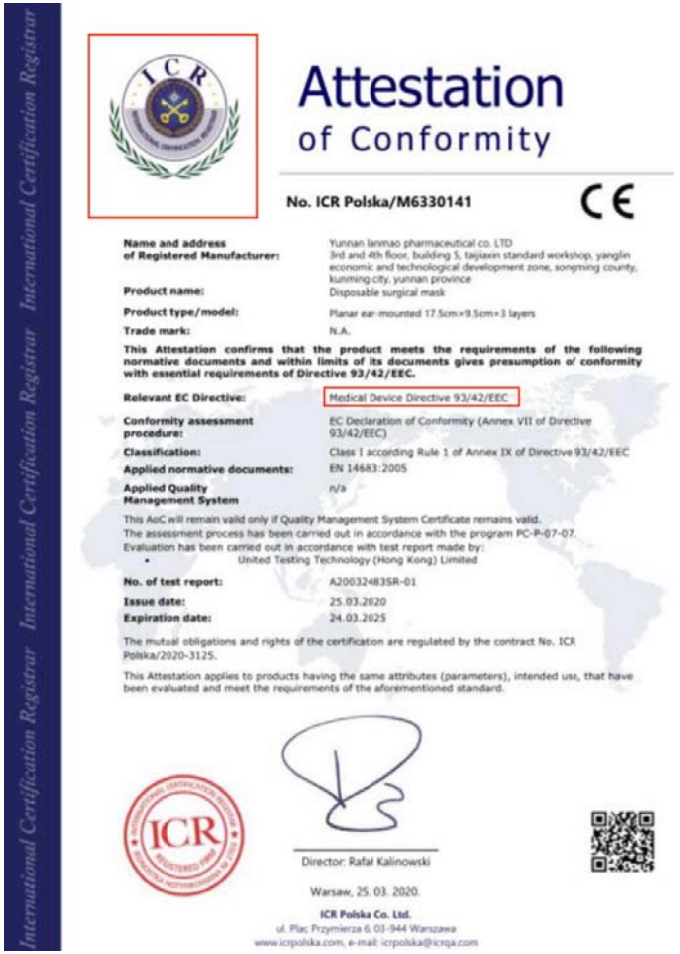
The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com



International Certification Registrar International Certification Registrar International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M6330141 CE

Name and address of Registered Manufacturer:	Yunnan lanmao pharmaceutical co. LTD 3rd and 4th floor, building 5, taijiaxin standard workshop, yanglin economic and technological development zone, songming county, kunming city, yunnan province
Product name:	Disposable surgical mask
Product type/model:	Planar ear-mounted 17.5cm×9.5cm×3 layers
Trade mark:	N.A.

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption o/ conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive:	Medical Device Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 14683:2005
Applied Quality Management System	n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test report made by:
- United Testing Technology (Hong Kong) Limited

No. of test report:	A200324835R-01
Issue date:	25.03.2020
Expiration date:	24.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020.

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

3.celab 是电气和电子设备产品的公告机构，在医疗器械和个人防护设备领域无相应资质，超范围发证，证书无效。

CELAB®
Via Maira snc
04100 Latina
Italy
celab@celab.com

celab

CERTIFICATE

Certificate Number **UCN** : **802118241927**
Job : J24364
Date of Issue : 2018-07-24
Certificate valid up to : 2022-07-23

Brand Name : Chnano
Type : ZN Mask
Model N : ZN6218, ZN6005, ZN8005, ZN8848, ZN2006

Manufacturer : China Nano Techonlogy Co.,Ltd.
Address : 4Floor, Hatching Building, Emigration Eco Industrial Park Management Committee, Fengjie, Chongqing, China

Standard Used : EN 149:2001+A1:2009

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
(EU)2016/425 Personal protective equipment (PPE)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : B-S180718239	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

www.celab.com

Doc 121 Voluntary Certificate rev 3.31

（二）本身不是 CE 证书

1.ECM 给企业颁发的一次性非灭菌（Not Sterile）医用口罩的文件审核证书。文档审查报告不是 CE 证书。

Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

Form QAT_10-M06, version 00, effective since March 25th, 2020

CE Documentation Review ECM

No. 3J200328M.QD80453

Holder: Qinghai Dongshuo Biotech Co., Ltd.
Room 1001 Building 1, No. 2 Weier Road, Qinghai Biotech Industrial Park, Xining, Qinghai, China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Mask for Medical Use (Not Sterile)
Model(s): Flat Ear Loop Mask of 3 Layers
Classification: Class I (Not Sterile) (accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 28 March 2020
Approver
ECM Service Director
Luca Belgrano

Expiry date 27 March 2025
Technical Expert
Amanda Payne

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖷 +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it

2.企业欧盟代表发的完成向荷兰官方注册企业产品的证明，不是认证证书。

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Sungo

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council directive 93/42/EEC, SUNGO performed all notification duties and responsibilities as the European authorized representative of:

Applicant: Fujian Yifa Healthcare Products Co., Ltd.
Address: Xinhan Industrial Area, Hanjiang District, Putian City, Fujian Province, China

The Manufacturer has provided SUNGO with all the appropriate declarations according to the 93/42/EEC Directive requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

Product(s): Disposable Medical Face Mask
Type(s): 175mm*95mm
Product Classification: Class I

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

The notification of aforementioned device has been completed by the European Representative in Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration. NOTIS number is CIBG-20200753.

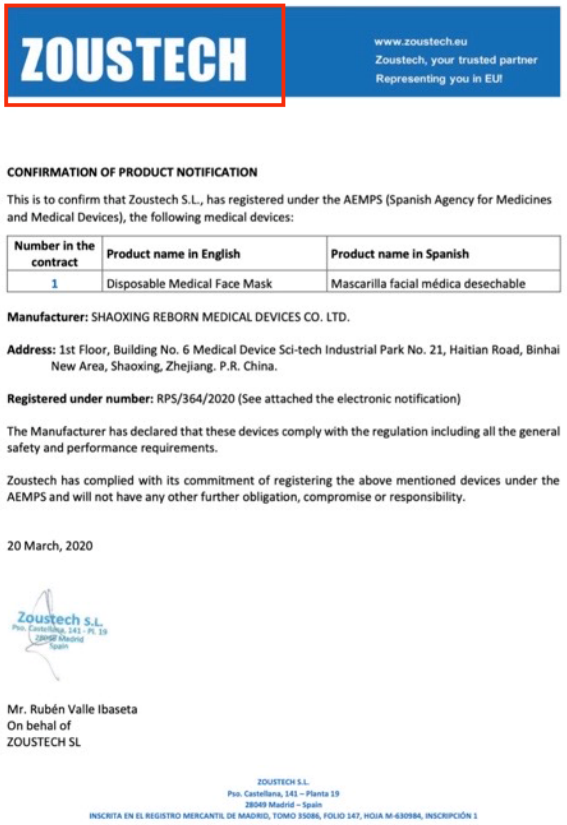
SUNGO Executive Director Sungo CERTIFIED

Issued: Apr. 01 2020
Cert. No.: EU281518
Expiration Date: Mar. 31 2025

CE
This is not a CE mark and is only provided as a template for informational purpose.

3.企业在西班牙找的代表机构 Zoustech 给产品在西班牙官方完成的注册证明，不是 CE 证书。Zoustech 专门做欧盟代表的业务。

注：产品出口欧盟需要有欧盟代表在官方做注册，这不是 CE 认证。



ZOUSTECH

www.zoustech.eu
Zoustech, your trusted partner
Representing you in EU!

CONFIRMATION OF PRODUCT NOTIFICATION

This is to confirm that Zoustech S.L., has registered under the AEMPS (Spanish Agency for Medicines and Medical Devices), the following medical devices:

Number in the contract	Product name in English	Product name in Spanish
1	Disposable Medical Face Mask	Mascarilla facial médica desechable

Manufacturer: SHAOXING REBORN MEDICAL DEVICES CO. LTD.

Address: 1st Floor, Building No. 6 Medical Device Sci-tech Industrial Park No. 21, Haitian Road, Binhai New Area, Shaoxing, Zhejiang. P.R. China.

Registered under number: RPS/364/2020 (See attached the electronic notification)

The Manufacturer has declared that these devices comply with the regulation including all the general safety and performance requirements.

Zoustech has complied with its commitment of registering the above mentioned devices under the AEMPS and will not have any other further obligation, compromise or responsibility.

20 March, 2020

Zoustech S.L.
Pso. Castellana, 141 - Pl. 19
28046 Madrid
Spain

Mr. Rubén Valle Ibaseta
On behal of
ZOUSTECH SL

ZOUSTECH S.L.
Pso. Castellana, 141 – Planta 19
28049 Madrid – Spain
INSCRITA EN EL REGISTRO MERCANTIL DE MADRID, TOMO 35086, FOLIO 147, HOJA M-630984, INSCRIPCIÓN 1

（三）无资质机构发放的无效证书

这些机构不是欧盟公告机构，更不具备欧盟医疗器械指令 MDD 93/42/EEC、MDR 医疗器械指令(EU) 2017/745 或(EU)2016/425 个人防护设备法规的相应资质，违规发放证书，证书均无效。

1. STS 不是公告机构，是国内从事电子电气产品检测机构，此证书与口罩无关，不是 CE 证书。

Certificate • 證明書 • 인증서 • diplômes • CertificadO • CERTIFICATE

Certification of Product Declarations

Application of the Council Directive 2011/65/EU and its amendment directive (EU) 2015/863 on the restriction of the use of certain hazardous substances in the electrical and electronic equipment

Certificate No.: C-STSGZ2003230001

Product Name	: Disposable surgical mask
Model(s) No.	: Y8
Series Model	: -
Brand Name	: -
Holder	: Hunan renrenhao Medical Device Technology Co., Ltd
Address	: In the home furnishing Industrial Park, Longling industrial concentration zone, Heshan District, Yiyang City, Hunan Province
Standard(s)	: IEC 62321-3-1:2013 IEC 62321-4:2013+A1:2017 IEC 62321-5:2013 IEC 62321-6:2015 IEC 62321-7-1:2015 IEC 62321-7-2:2017 IEC 62321-8:2017
Report No.	: STSGZ2003230001

Validation of the certificate are subject to:

- The compliance to the surveillance requirements

- Conditions of restriction as stipulated in the test report

The applicant of the certificate is authorized to use this certificate in connection with EC declaration of conformity to the Directive. The certificate is only applicable to the equipment described above.

RoHS

Approved by: 31-Mar-2020 Chemical Test Manag

APPROVAL

Guangzhou Depuhua Test Services Co., Ltd.
A301, 3/F., Xinhui Building, Guangpu, Shiqiu, Panyu District, Guangzhou, Guangdong, China
Tel: +86-(0)20 6664 1688 Fax: +86-(0)20 6664 1690 E-mail:stsgz@stsapp.com
Web: Shenzhen: www.stsapp.com Guangzhou: www.stsgz.com

2. BSI TESTING 不是公告机构，证书无效。

Certificate - Сертификат - 證明書 - Certificat - 증명서 -

Certificate of Compliance

No. BST2003137300015C

Certificate's Holder: Guizhou aikangjia Medical Technology Co., Ltd Gui'an New Area Branch
Building 19, Standard Workshop, South Park, High End Equipment Manufacturing Industrial Park, Gui'an New Area, Guizhou Province

Certification Mark: BST Testing

Product: Disposable Protective Mask
Model(s): KN90, KN95, K-GB01-001

Verification to: Standard: EN 149:2001+A1:2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: the product(s) has been verified on a voluntary basis, the product(s) satisfies the requirements of the Certification Mark of BST., In reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the BST regulation about its release and its use. The regulation can be found at www.bst-test.com. The Certificate of Compliance can be checked for validity at www.bst-test.com.
This verification doesn't imply assessment of the production of the product(s).
Additional information, clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the manufacturer is responsible to start the CE Marking Certification Procedure through an appointed Notified Body and to perform all the necessary activities, as required by the Directive and accredited by the Notified Body, before placing the CE Mark on the product(s).

Date of Issue 02 April 2020

Expiry date 02 April 2023
Deputy Manager
Dantsee

BST Testing Service International Co., Limited
Flat/RM 18026 18/F Fortress Tower 250 King's Road North Point HK
Certificate Search: http://www.bst-test.com Tel:00852-40845910 E-mail:tecc.bst@gmail.com

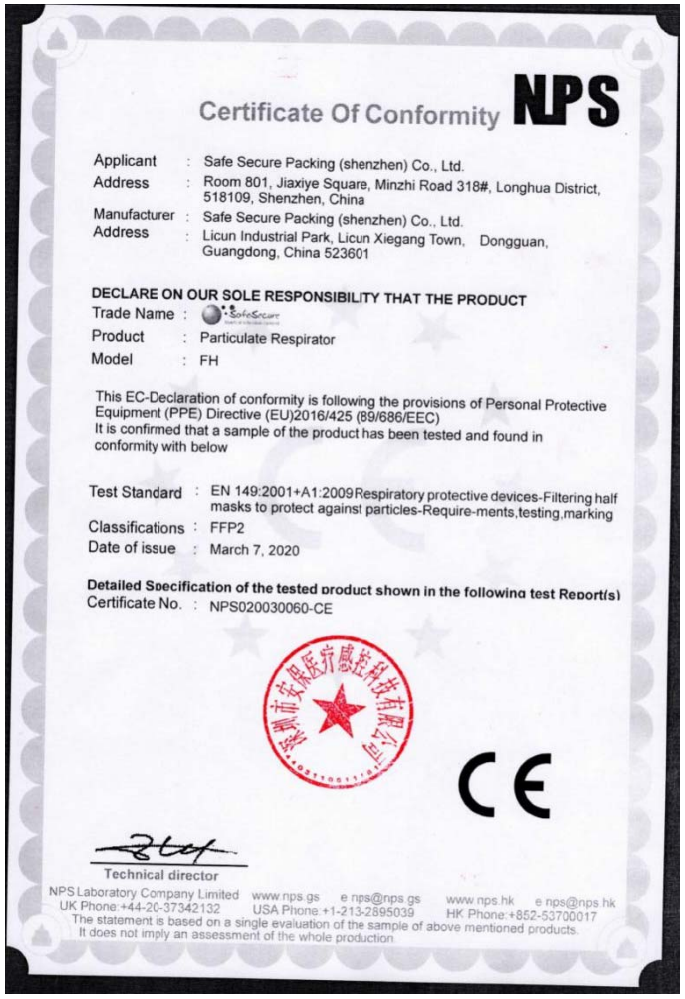
3. TUV-world 不是公告机构，且一次性非无菌医用口罩应该走自我声明，不需要公告机构去认证，证书无效。

CERTIFICATE OF COMPLIANCE

No.: CE2020T9340100

TUV-WORLD ECC CERTIFICATION SERVICE,S.L.
ADDRESS:PS DE LA CASTELLANA 114, 28046-MADRID,SPAIN
TEL: + 34 912 127 295 E-MAIL: info@tuv-world.es

4. NPS 不是该产品领域的公告机构，证书无效



Certificate Of Conformity NPS

Applicant : Safe Secure Packing (shenzhen) Co., Ltd.
Address : Room 801, Jiaxiye Square, Minzhi Road 318#, Longhua District, 518109, Shenzhen, China
Manufacturer : Safe Secure Packing (shenzhen) Co., Ltd.
Address : Licun Industrial Park, Licun Xiegang Town, Dongguan, Guangdong, China 523601

DECLARE ON OUR SOLE RESPONSIBILITY THAT THE PRODUCT
Trade Name : SafeSecure
Product : Particulate Respirator
Model : FH

This EC-Declaration of conformity is following the provisions of Personal Protective Equipment (PPE) Directive (EU)2016/425 (89/686/EEC)
It is confirmed that a sample of the product has been tested and found in conformity with below

Test Standard : EN 149:2001+A1:2009Respiratory protective devices-Filtering half masks to protect against particles-Require-ments,testing,marking
Classifications : FFP2
Date of issue : March 7, 2020

Detailed Specification of the tested product shown in the following test Report(s)
Certificate No. : NPS020030060-CE

Technical director

NPS Laboratory Company Limited www.nps.gs e nps@nps.gs www.nps.hk e nps@nps.hk
UK Phone:+44-20-37342132 USA Phone:+1-213-2895039 HK Phone:+852-53700017
The statement is based on a single evaluation of the sample of above mentioned products.
It does not imply an assessment of the whole production

5. CIC 不是欧盟公告机构，是深圳一家测试机构，属于无效证书。

CERTIFICATE ◆ CERTIFICATE ◆ CERTIFICATE

CIC

CERTIFICATE OF CONFORMITY

EU - Personal protective equipment (PPE)-
No. CIC200305016-ZJ(REV2)-ZS

Applicant	:	Shenzhen Missadola Technology Co., Ltd.
Address	:	602# longyuan building industry road minzhi street longhua Xinqu district Shenzhen city China
Manufacturer	:	Shenzhen Missadola Technology Co., Ltd.
Address	:	602# longyuan building industry road minzhi street longhua Xinqu district Shenzhen city China
Product	:	KN95 MASK
Trade Name	:	N/A
Model(s)	:	2626-1
Classification	:	FFP2 NR D
Test Report No.	:	CIC200305016-ZJ(REV2)
Test Standards	:	EN 149: 2001+ A1: 2009

The tests that base on the above designated product Complies with the essential requirements of Regulation 2016/425/EU.

The test results apply only to the particular sample tested and to the specific tests carried out. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

Other relevant Directives have to be observed.

CE

CIC TESTING SERVICE CIC INTERNATIONAL

Hale Zhao (Chief engineer)
March 06, 2020

Shenzhen CIC Testing Technology Co., Ltd
Add: No.102, Floor 1, Building A, No. 26 of Xinhe Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China
Web: http:// www.soncap-saso.com Tel: 4008-707-263 Fax: +86-0755-23208027

6. Amtre Veritas 不是欧盟公告机构，证书无效。

AMTRE VERITAS STANDARD TECHNICAL TESTING LTD

amtre veritas

Certificate of Compliance

With European Directives

Applicant Manufacture: WENZHOU READSUN OPTICAL CO.,LTD.
Add.: 3F , NO.59 HAOXIN ROAD , LOUQIAO INDUSTRY PARK , OUHAI , WENZHOU , ZHEJIANG ,CHINA
Product Name: Safety Goggles
Model/type: Safety Goggles Series

The submitted sample of the above product has been tested for CE marking according to the following European Directives:

(EU) 2016/425 PPE Directive

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN 166: 2002 **Personal eye protection - Specifications**
EN 167: 2002 **Personal eye protection - Optical Test Methods**
EN 168: 2002 **Personal eye protection - Non - Optical Test Methods**
EN 1938: 2010 **Personal eye protection - Goggles for motorcycle and moped users**

The referred report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The CE marking as shown below can be affixed on the product.

Certificate No.: AV-WZRS20200330075

Date: Mar 30 ,2020

for amtre veritas:

General Manager

CE

amtre veritas: No. 96 holcroft house ingrave street london
Tel:00442078010996 Fax:00442075014189
Http://www.amtre-veritas.com PC:SW11 2SQ
E-mail:amtreveritas@gmail.com

COMMON SEAL

7. ENC 不是欧盟公告机构，是广州一家测试机构，证书无效。

EC-Certification of Conformity

ENC

Certification of Conformity

PERSONAL PROTECTIVE EQUIPMENT - (EU) 2016/425

Registration No.: ENC2003111GZ54

Applicant	:	Dongguan Zhijie Automation Equipment Co., Ltd.
Applicant Address	:	Room 301, Building 301, No. 5 Xinji Road, Nancheng Street, Dongguan City, Guangdong Province, China
Product Designation	:	Protective Face Mask
Model Number	:	KN85
Brand Name	:	舒尚安
Classification	:	FFP2
Manufacturer	:	Dongguan Zhijie Automation Equipment Co., Ltd.
Manufacturer Address	:	Room 301, Building 301, No. 5 Xinji Road, Nancheng Street, Dongguan City, Guangdong Province, China

The submitted products have been tested by us with the listed standard and found in compliance with the following European Standards:

Directive	Applied Standards	Test Report No.
PPE (EU) 2016/425	EN 149:2001+A1:2009	ENC2003111GZ54E1

This certificate is based on an evaluation of a sample of the above mentioned product. Technical report and documentation are at the licence applicant's disposal. This certificate does not imply assessment of the series-production of the product. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

CE

Ray Zhou / General Manager
Date of Issue: Mar. 31, 2020

East Notice Certification Service Co., Ltd.
1/F, Maohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+86-020-8256 8534 Fax:+86-020-8256 8534 E-mail:enc@enc-lab.com Web: www.enc-lab.com

8. sts 不是欧盟公告机构，证书无效。

STS INSPECTION & CERTIFICATION LIMITED

Certificate of Conformity

LIST OF DIRECTIVE S/REGULATIONS/STANDARDS(as declared by the manufacturer itself)Personal Protective Euipment 2016/425

NO:U20200320200008001

Holder of Certificateolder : Shandong Youyikang Protective Equipment Co.,Ltd
No. 3 , yuanjiatuan village , Baicheng Town , Gaomi City , Weifang City , Shandong Province , China.

Machine	:	Protective Mask
Model(s)	:	KN95
TCF No.	:	SCCTCF20031922-PPE
Test Standards	:	EN 149:2001+A1 : 2009

The label of the CE Marking below should be dot less than 5mm height . CE Marking and EC Declaration of conformity are duties for the manufacturer or its applicant who puUts the product on the market .This one is responible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsonly included into specific Directives or Regulations will be necessary to appoint a Notified Body.
NOTE :The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted .The latest revision of the Regulation is available and can be downloaded from the website www.STS-UK.org.This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO(IEC 17065 :2012)or European Regulation 765/2008 .
REMARK : certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the STS Mark (at point 3) on their products , even if it doesn't imply any assessment on the safety and compliance of the poduct . STS declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

CE

Technical certifier : williams

Date of Issue
: 20th Mar , 2020

STS INSPECTIONG & CERTIFICATION LIMITED
UNIT G25 WATERFRONT STUDIOS 1 DOCK ROAD LONDON
UNITED KINGDOM E16 1AH
http://www.STS-UK.org Email: STS@STS-UK.org

9.HTT 不是欧盟公告机构，是深圳一家私营企业，证书无效。

SHENZHEN HTT TECHNOLOGY CO.,LTD.
HOTLINE: 400-6655-351
WWW.HTTPRC.COM

Certificate of Conformity

Certificate No.	:	HTT202003057L
Applicant	:	Shenzhen Source Innovation technologies Co. Ltd.
Applicant Address	:	Building A6, No.87 Tongxin Road. Tongxin Community, Longgang District, Shenzhen City, China.
Manufacturer	:	Shenzhen Source Innovation technologies Co. Ltd.
Manufacturer Address	:	Building A6, No.87 Tongxin Road. Tongxin Community, Longgang District, Shenzhen City, China.
Product	:	Particulate Respirator
Model No.	:	S9402（XL）
Trademark	:	固源

The above products have been tested by us with listed standards and found in compliance with the council PPE (Personal Protective Equipment) (EU)2016/425. It is possible to use CE marking to demonstrate the compliance with this Personal Protective Equipment.

Test standards:	Report(s) Number	Issued By	Issued Date
EN149: 2001+A1: 2009	HTT202003057LR	HTT	Mar.10,2020

This certificate of conformity is not transferable and based on an evaluation of a sample of the above mentioned product.

CE

Authorized Signer: Kevin Yang

Kevin Yang/Senior Manager

Date: Mar.10,2020

TEL: 0755-23595200 FAX: 0755-23595201
1F, B BUILDING, HUAFENG INTERNATIONAL ROBOTICS INDUSTRIAL PARK, GUSHU, XIXIANG STREET, BAO'AN DISTRICT, SHENZHEN

10.iTC 不是欧盟公告机构，是深圳一家测试机构，证书无效。

Certificate · 認證證書 · 인증 증서 · diplomes · certificado

iTC

CE RTIFICA OF COMPLIANCE

Ref. No.: 20ITC0319023

Applicant:	Shandong Se Future Chemical Trading Co.,Ltd
Address:	Haikou street 256, kaixuan shangwu zhongxin, No.913,Qingdao,China
Manufacturer:	Shandong Se Future Chemical Trading Co.,Ltd
Address:	Haikou street 256, kaixuan shangwu zhongxin, No.913,Qingdao,China
Product designation:	Respirators&Mask
Model No.:	KN95、KN90、KF94、RMK-I、RMK-II、RMK-III、RMD-I、RMD-II、RMD-III
Brand Name :	Rosefor
FFP Class:	FFP1, FFP2, FFP3
Testing Standard:	EN149:2001+A1:2009

The type tested complies with the provisions laid down in the drective (EU)2016/425 Personal protective equipment (PPE).

CE

Approved by/Date: *Mar.20, 2020*

DepartmentManager

Shenzhen iTC Product Testing Co., Ltd.
2nd Floor, Building A7 , Xinhe XinxingThird Industrial Area, Fuhai Road, Fuyong Street Bao'an District, Shenzhen, China
Tel: (86)-0755-33138690 Fax: (86)-0755-23071003 http://www.itclab.cn/

Certificate · 認證證書 · 인증 증서 · diplomes · certificado

11.BTK 不是欧盟公告机构，是广州一家测试机构，证书无效。

欧标

BTK

Certificate of Conformity

No.: BTK20200210001PPE

The following product has been tested by us with the listed standards and found in conformity with the council CE directive (EU) 2016/425. It is possible to use CE marking to demonstrate the conformity with this CE Directive (EU) 2016/425.

Applicant:	Lanshan shendun Technology Co., Ltd.
Address:	No.5-7, Leather Industry Park, Xiangjiangyuan, Lanshan County, Hunan Province
Manufacturer:	Lanshan shendun Technology Co., Ltd.
Address:	No.5-7, Leather Industry Park, Xiangjiangyuan, Lanshan County, Hunan Province
EUT:	Non-powered air-purifying particle respirator(KN95 Masks)
M/N:	SD-KN95-01, SD-KN95-02, SD-KN95-C01, SD-KN95-C02
Test Standards:	EN149:2001+A1:2009

CE

Guangzhou Bestek Testing Services Co., Ltd. APPROVED (Manager)

Mar. 02, 2020

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the products same as the tested sample above mentioned only.

Guangzhou Bestek Testing Services Co., Ltd.
Unit F503, 5th Floor of Xinshui Keng Trade Square, No.10 of Shixin Road, Dalong Street, Panyu District, Guangzhou City, Guangdong Province, P.R. China.
☎ + 86 20 3993 5456 + 86 20 3993 5356 info@btktest.com.cn Http://www.btktest.com.cn

12..Micez 不是欧盟公告机构，是上海一家测试机构，证书无效。

CERTIFICATE

of Compliance

Certificado de Conformidade - Сертификат соответствия - Konformitätserklärung

CERTIFICATE NO.: SHHS-2020022701

Certificate's Holder :	DONGGUAN TEAMSUN GARMENT CO.,LTD.
Address:	Room 202，Building 6，NO.8，Wanjiang Chuangye industrial road，Wanjiang District，Dongguan City，Guangdong Province，China
Product :	Single-use face mask
Model(s) :	M01002,M01001,M01003,M01004
Directives :	Personal protective equipment (EU) 2016/425
Standards :	EN 149:2001+A1:2009
Test Report no.:	SHHS-01525-PPE

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of MICEZ, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the MICEZ regulation about its release and its use. The regulation can be found at www.maixize.com. This Certificate of Compliance can be checked for validity at www.maixize.com.
This verification doesn't imply assessment of the production of the product(s).
We attest that a TCF for the Marking process is in place. Whereas the Manufacturer is Responsible to start the Marking Certification Procedure and to perform all the necessary activities, as required by the Directive before placing the Mark on the product(s).

CE

ISSUED:
March 24,2020

Micez Attestation &Certification

Manager:Thomas.Peng

Shanghai MICEZ Equipment Testing & Technical Co., LTD
Road 402, Huifeng Business No.6111 Zhongchun Road,
Minghang District, Shanghai, China
Office:+86 21 52968370/52968373/52968375

13. Huawin 不是欧盟公告机构，是深圳一家测试机构，证书无效。

Certificate Number: HW20200325041S
Personal Protective Equipment Regulation
(EU) 2016/425

Certificate Of Compliance

Applicant : [redacted]
Address : [redacted]
Manufacturer : [redacted]
Address : [redacted]
Product : FFP2 Faxe Mask
Model : KN95

The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European Directives.

EN 149: 2001+A1:2009

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.
This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.

CE

Manager: Gui Su
Date: March 25, 2020

Shenzhen Huawin Testing Certification Co., Ltd.
Add: 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China
Http://www.huawinlab.com E-mail: info@huawinlab.com

14. LTT 不是欧盟公告机构，是深圳一家测试机构，证书无效。

CERTIFICATE OF COMPLIANCE

PRODUCT NAME : Single-use face mask
MODEL NUMBER : KN95
APPLICANT : Anhui Huaguotang Biotechnology Co., Ltd.
APPLICANT ADDRESS : 188 Hehuan Road, Bowu Industrial Park, Bozhou City
MANUFACTURER : Anhui Huaguotang Biotechnology Co., Ltd.
MANUFACTURER ADDRESS : 188 Hehuan Road, Bowu Industrial Park, Bozhou City
Cert. No. : LTT20200319PE01
Test Standards : EN 149:2001+A1:2009

The tests that base on the above designated product Complies with the essential requirements of Regulation (EU)2016/425 Personal protective equipment (PPE) .
The test results apply only to the particular sample tested and to the specific tests carried out.
Specifically to the sample investigated in our test reference number only.
The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.
Other relevant Directives have to be observed.

Signature: Lance
Date: Mar.19,2020

CE

Shenzhen LTT Testing Technology Co.,Ltd
http://www.ltt-lab.com TEL:86-755-27924028 FAX:86-755-29129709

15. VIC 不是欧盟公告机构，证书无效。

CERTIFICATE OF CONFORMITY

Certificate No.:

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

Applicant:

Manufacturer:

Product: Disposable face mask
Model No.: 17.5CM*9.5CM
Report No.: DN20200314-JSY25-CE-S

Complies with the requirements of the **Regulation (EU) 2016/425 Personal Protective Equipment(PPE)** The submitted products have been tested by us and found in compliance with the following European Standards:

EN 149:2001+A1:2009

This certificate of conformity is based on an evaluation of a sample of the above mentioned products. It does not imply an assessment of the whole production. The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Signature: Steven White
Steven White
Date of issue: Mar. 15, 2020
Expiry Date: Mar. 14, 2025

VIC TESTING AND CERTIFICATION LTD
Add: CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K
Email: info@victesting.com Website: www.victesting.com

16. JZ-CERT 不是欧盟公告机构，证书无效。

Verification OF CONFORMITY

Company Name	:Heze Ruifukang Pharmaceutical Products Co., Ltd.
Company Address	Xiaozhuang North (Anhuang Road East), Anxing Town, Mudan District, Heze city, Shandong province, CHINA
Related Regulation	: PPE Regulation (EU) 2016/425
Standards Product	: EN149:2001+A1:2009
Name	: Disposable Face Mask
Classification:	: Category I
Model	: 17.5x9.5cm,17.5x9.0cm, 16.5x9.5cm, 16.5x9.0cm, 14.5x 9.0cm, 14.5x7.0cm, 12.5x9.0cm

The certification is valid in accordance with the test report JZCF030803-PPE and when the product is manufactured in accordance with the tested sample.

According to Article 19 of the PPE Regulation, for category I PPE, the manufacturer is required to follow the internal control procedure set out in Annex IV to establish the technical documentation and to draw up the EU Declaration of Conformity to confirm that his product complies with the health and safety requirements of the Regulation.
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives:
PPE Regulation (EU) 2016/425 Category I

The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only forthe products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

Certificate NO. JZ86200318505

Issued Date: 18 Mar. 2020

General Manager Yrangdi

JZ-CERT. SH OFFICE

Copyright of this Certificate is owned by jz-cert and may not be reproduced other than in full and with theprior approval of the General Manager. Use of this certificate is subjected to JZCERT regulation available on JZCERTweb site.

Versoin_01 Website：www.jz-cert.com Email：admin@jz-cet.com

17. OCT 不是欧盟公告机构，是广州一家测试机构，证书无效。

Certificate of Conformity

Certification No: OCT20200319408P

Applicant:

Address:

Manufacturer:

Address:

Certification Marking: CE-PPE

Product Description: Kn95 protective mask

Model: KN95

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards	:	EN 149:2001+A1:2009

When tested as specified, the submitted sample complies with Personal Protective Equipment (PPE) – Regulation (EU) 2016/425

The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.

CE

Authorized Signer:

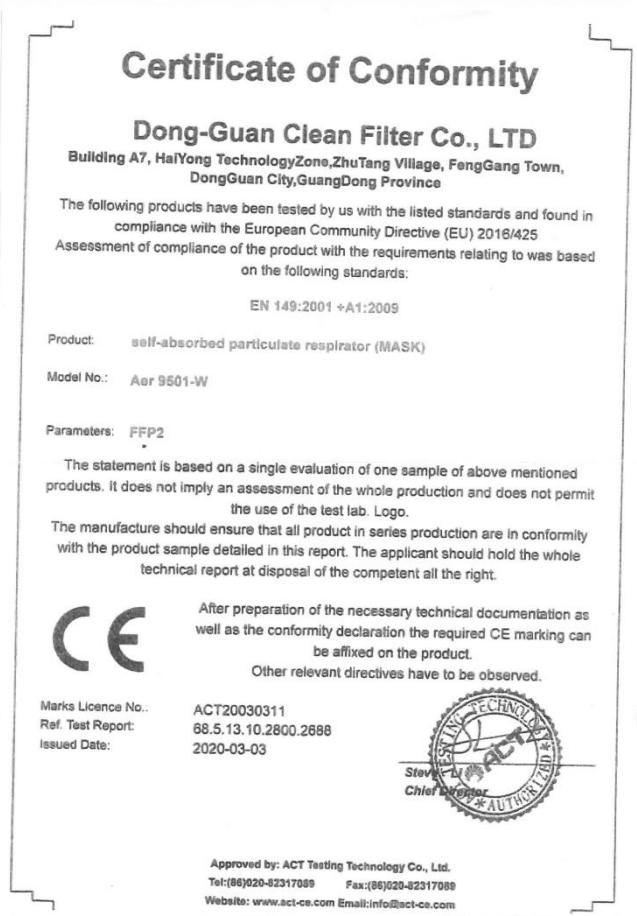
Mar 19, 2020

Oct Technology Testing Co., Ltd.

637,No. 56, zhongyun Road,Panyu District,Guangzhou,Guangdong Province,China

TEL:020-89015652,888@oucetesting.com,www.oucetesting.com

18. ACT 不是欧盟公告机构，证书无效。



Certificate of Conformity

Dong-Guan Clean Filter Co., LTD

Building A7, HaiYong TechnologyZone,ZhuTang Village, FengGang Town, DongGuan City,GuangDong Province

The following products have been tested by us with the listed standards and found in compliance with the European Community Directive (EU) 2016/425

Assessment of compliance of the product with the requirements relating to was based on the following standards:

EN 149:2001 +A1:2009

Product: self-absorbed particulate respirator (MASK)

Model No.: Aer 9501-W

Parameters: FFP2

The statement is based on a single evaluation of one sample of above mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test lab. Logo.

The manufacture should ensure that all product in series production are in conformity with the product sample detailed in this report. The applicant should hold the whole technical report at disposal of the competent all the right.

CE

After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product.

Other relevant directives have to be observed.

Marks Licence No.: ACT20030311

Ref. Test Report: 68.5.13.10.2800.2688

Issued Date: 2020-03-03

Chief Director

Approved by: ACT Testing Technology Co., Ltd.

Tel:(86)020-82317089 Fax:(86)020-82317089

Website: www.act-ce.com Email:info@act-ce.com

19. XW-CERT 不是欧盟公告机构，是深圳一家公司，证书无效。

XW-CERT

Certificate of Conformity

Certificate Number: XWSC2003030201

Applicant : Zhongshan xinmeite household technology co., ltd.

402# Donghai 5th Road , Yongyi Village, Dongfeng Town, Zhongshan City

Manufacturer : Zhongshan xinmeite household technology co., ltd.

402# Donghai 5th Road , Yongyi Village, Dongfeng Town, Zhongshan City

Product : Protective Mask

Model No. : KN95

Trade Mark : ROYALGODDESS

Test Standards : EN 149:2001+A1:2009

Test Report No. : XWSR2003030201

Date Of Issue: 2020/03/11

The sample described aboved has been tested by us with the listed standards and found in conformity with the standards : EN 149:2001+A1:2009.This certificate is part of the full test reports and should be read in conjunction with report NO.. XWSR2003030201.

CE

Marin Wang/Manager

Mar. 11, 2020

Shenzhen XinWei Certification Service Co.,Ltd

Address: 5th Floor, Xusheng R&D Building, Gonghe Industrial Road, Xixiang Street, Baoan District, Shenzhen

Email: service@xwcert.com www.xwcert.com

20. ATL 不是欧盟公告机构，是深圳一家测试机构，证书无效。

ATL

E-mail: atl@atllab.org
Web: Http://www.atllab.org

Floor 5,Genesis Zhongye Building,No.22, Puzai Road,Pingdi Street,Longgang District, Shenzhen,Guangdong,China (518000)

EC-Certification of Conformity

PPE Directive (EU) 2016/425

Registration No.: ATL202004081121

Applicant:

Applicant Address:

Manufacturer:

Manufacturer Address:

Product Designation: KN95 Stereo Protective Mask

Brand Name: FIPILOCK

Model / Series Models: FP -15

Requirement	Applied Standards	Result
PPE Directive	EN 149:2001+A1:2009.	Conform

CE

Signed by Qu

Issue Date: A

Recognized by Shenzhen ATL Testing Technology Co., Ltd., in accordance with the PPE Directive (EU) 2016/425. This certificate doesn't imply assessment of the production. The Applicant of the certificate is authorized to use this certificate in connection with EC declaration of conformity to the Directive. The certificate is only applicable to the equipments described above. This certificate shall not be re-produced except in full without the written approval of Shenzhen ATL Testing Technology Co., Ltd.
Note: This certificate is part of the full test report(s) and should be used in conjunction with it.

21. TMC 不是欧盟公告机构，是深圳一家测试机构，证书无效。

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TMC
Access to global market

Certificate of Compliance

Certificate No.:	TMC200326122-S
Applicant/ Address:	**Zhongshan Tichar Trading Co., Ltd** No.8 Jinying Road Tan Zhou Town , ZhongShan City, GuangDong Province
Manufacturer/ Address:	**Zhongshan Zhixin Medical Equipment Co., Ltd.** Area A, 1/F, No. 2 Fengxiang Down Street, Tanzhou Town, Zhongshan City, Guangdong Province
Product Name:	**Disposable respirator**
Trade Name:	N/A
Model/Item Number :	ZXKN95
Rated:	--
Classification:	Class I, FFP2
Date and Number of Test Report:	March 27,2020 TMC200326122-S
EC-directive:	PPE Directive (EU) 2016/425
Test Standard:	EN149:2001+A1:2009

Conclusion

This Declaration of PPE Compliance has been granted to applicant based on the results of tests, performed by Laboratory of TMC Testing Services (Shenzhen) Co., Ltd. on sample of the above-mentioned product in accordance with the provisions of the relevant specific standards and the PPE Directive (EU) 2016/425. It is possible to use CE marking to demonstrate the compliance with this Directive.

Place and date of issue: Shenzhen, March 27,2020

TMC Testing Services (Shenzhen) Co., Ltd.
1st Floor, Block A1, Zone A, Xinshidai Gongrong Industrial Park, No. 2, Shihuan Road, Shiyan Street, Baoan District, Shenzhen, China
Tel: +86-755- 86642861
Email:cert@tmc-lab.com
Http://www.tmc-lab.com

Bauart geprüft TMC Product Safety Type approved

Lab Director
Lemon Rao

CE

TMC

22. Youbest 不是欧盟公告机构，是深圳一家测试机构，证书无效。

CERTIFICATE

Fulfills testing requirement of the PPE (Personal Protective Equipment) Directive (EU) 2016/425.
Registration No.: YB200331229XY-PPE-A1
Report No.: YB200331229XY-PPE-B1

YouBest

Certificate of Compliance

Applicant	:	Zhejiang Hanyang Medical Equipment Co., Ltd.
Address	:	No. 10, Group 1, Shuizhuyu, Baihe Town, Tiantai County, Taizhou City, Zhejiang Province, China
Manufacturer	:	Zhejiang Hanyang Medical Equipment Co., Ltd.
Address	:	No. 10, Group 1, Shuizhuyu, Baihe Town, Tiantai County, Taizhou City, Zhejiang Province, China
Product	:	KN95 mask
Trademark	:	瀚洋
Model No.	:	KN95 Mask, N95 Mask
Classification	:	FFP2

The submitted sample of the above equipment has been tested and found to comply with the following standards:

EN 149:2001+A1:2009
Respiratory protective devices – Filtering half masks to protect against particles – requirements, testing marking

The test results apply only to the particular sample tested and to the specific tests carried out.
Technical report and documentation are at the holder disposal
This certificate applies specifically to the sample investigated in our test reference number only.
It is possible to use CE marking to demonstrate the compliance with this PPE directive. Other relevant directives have to be observed.

CE

YouBest TESTING TECHNOLOGY CERTIFICATION

Eric Sang
Certification Manager

Date : March 31, 2020

Youbest Testing Technology Co., Ltd.
1st Floor, Building D6, Xiakeng Road, Tongxin Community, Baolong Street, Longgang District Web: https://www.youbest-lab.com Tel: 400-168-1910

23. Shenzhen Tian Hai Test Technology 不是欧盟公告机构，是深圳一家测试机构，证书无效。

Shenzhen Tian Hai Test Technology Co.,Ltd.

CE Certificate of Conformity

Certification number: TH20CC-176S Report number: TH20CR-176S

Shenzhen Tian Hai Test Technology Co.,Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant: **Liaoning shengjingtang biotechnology Co.,Ltd.**

Address: 118-3 leye street, shenbei new district, shenyang city, liaoning province, China

Manufacturer: **Liaoning shengjingtang biotechnology Co.,Ltd.**

Address: 118-3 leye street, shenbei new district, shenyang city, liaoning province, China

Product: **Medical Protective Mask**

Trade mark:

Model: Folding type

And, in accordance with the following applicable directives:

(EU) 2016/425 Personal Protective Equipment(PPE)

This product has been assessed against the following applicable standards;

Standard: EN 149:2001+A1:2009

Therefore, Shenzhen Tian Hai Test Technology Co.,Ltd. hereby acknowledges that the applicant may issue a DECLARATION of CONFORMITY and apply the CE marking in accordance with European Union Rules.

Attestation by:

Thomas Wong

Date of Issued: March 16, 2020

4F,A3 BLDG,The Silicon Valley Power intelligent terminal industrial park,Guan lan street,Longhua district,Shenzhen

Tel:+86-755-86615100 Fax:+86-755-86615105 http://www.tianhaitest.com

24. UK INSPEC INTERNATIONAL CO.LTD 不是欧盟公告机构，证书无效。

UK INSPEC INTERNATIONAL CO.,LTD

The query url:Http://www.isp-uk.com

ISP CERTIFICATION

Declaration Of Conformity

Applicant : DANDELION GROUP PTY LTD

Address : 73 ALFRED ROAD,CHIPPING NORTON,SYDNEY NSW 2170 AUSTRALIA.

Manufacturer: Fujian Kang Chen Daily Necessities Co, Ltd.

Address : No.55 Houmao industrial park, Fengze District, Quanzhou City, Fujian Province CHINA

DECLARE ON OUR SOLE RESPONSIBILITY THAT THE PRODUCT

Product Name : Disposable Protective Face Masks /N95 RESPIRATORY MASKS

Main Test Model : K0450

Additional Model : K1297.K0467

Test Standard : EN 149:2001+A1:2009

The EUT described above has been tested by us with the listed standards and found in compliance with the council PPE directive 89/686/EEC . It is possible to use CE marking to demonstrate the compliance with this MDD Directive.
The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production.

Date of issue: Mar 16,2020 Expiry Date: Mar 15,2025

Detailed Specification of the tested product shown in the following test

Certificate No. : JAT-20(03)B301-PPE

Issued by:

Laboratory Manager

CE

The statement is based on a single evaluation of the sample of abovementioned products. It does not imply an assessment of the whole production.

25. bel 不是欧盟公告机构，是深圳一家测试机构，证书无效。

Shenzhen BEL Technology Co.,Ltd.
Add: 3rd Floor, Xingfu Building, Tongfuyu Industrial Zone, Shiyan Town, Bao'An District, Shenzhen, Guangdong, China.

Declarations of Conformity

Certificate Number: BEL20200000101829

Applicant	:	FUJIAN SOUTHEAST ART PAPER CO.,LTD.
Address	:	HUALIN ECONOMIC DEVELOPMENT ZONE, PUTIAN CITY(SHANPAI COUNTRY, HUATING TOWN, CHENGXIANG DISTRICT),FUJIAN,CHINA.
Manufacturer	:	FUJIAN SOUTHEAST ART PAPER CO.,LTD.
Address	:	HUALIN ECONOMIC DEVELOPMENT ZONE, PUTIAN CITY(SHANPAI COUNTRY, HUATING TOWN, CHENGXIANG DISTRICT),FUJIAN,CHINA.
Product	:	High Filtration Efficiency Particulate Protection Respirator
Model	:	DN-65,DN-66
Classification	:	FFP2
Test Standard	:	EN149:2001+A1:2009

The EUT described above has been tested by us with the listed standards and found in compliance with the council PPE directive 2016/425/EU. It is possible to use CE marking to demonstrate the compliance with this PPE Directive.
It is only valid in connection with the test report number: BEL20200000101829

CE

Manager
Mar. 27, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant. Directives have to be observed.
Tel:+86-755-27808385， Email:Lucky@belemc.cn,
Web:Http//www.belemc.com www.belemc.cn

26. Mosen 不是欧盟公告机构，是广州一家测试机构，证书无效。

MOSEN

CERTIFICATE OF CONFORMITY

Certificate No.: MOS2003209955S
TCF(s)or Test Report(s) No.:MOS2003209955S

Applicant	:	Fujian Angel Technology Co,LTD
Address	:	No.339, Qiyang village , Heshang town,, Changle district,Fuzhou city, Fujian Province
Product	:	Disposable Face Mask
Model(s)	:	17.5cm X 9.5 cm -3P , AGLDFM001

Reference to EC Directive:
PPE Directive EU 2016/425
EN 149:2001+A1:2009

REMARKS

Assessment of the product(s) and the production is not covered by this verification, which has been carried out on a voluntary basis. It is duty and fully responsibility of the manufacturer to carry out all necessary safety assessment of the product(s) according to all related EC Directive and Standard(s) before putting into market/service, affixing CE mark and issue EU Declaration of Conformity. The manufacturer shall affix CE mark on the product(s) according to 2006/42/EC Article 16 and Annex III, only if the product(s) fulfill the relevant essential health and safety requirements and the drawn-up EU Declaration of Conformity. Technical File should be drawn for each type/model of related product(s) by the manufacture and/or his authorized representative in order to assure conformity with the essential health and safety requirements which demonstrate that the machinery complies with the requirements of the related directives/standards and must be complied in one or more official Community languages. Before placing machinery into market/service, the manufacturer or his authorized representative shall ensure that the Technical File in accordance with related directives/standards is available.
The manufacturer or his authorized representative shall keep Technical File and EU Declaration of Conformity available for a period of ten years from the last date of manufacture of the machinery.
The certificate consists of 1(one) page.

CE

Center of Testing Certification
MOSEN
Manager
March 04, 2020

Mosen Detection Technology Co., Ltd.
No.28-C2010, Xintang Street, Tian'he District, Guangzhou, China
TEL: 400-200-859 Internet: www.mosen-cert.com

27. ZUOCE CERTIFICATION AND TESTING CENTER 是上海一家测试机构，不是欧盟公告机构，证书无效。

ZUOCE CERTIFICATION AND TESTING CENTER
Providing Professional Service for Safety and Health

CERTIFICATE OF CONFORMITY

Certificate No.	:	ZUOCE200317262
Company Name	:	Dezhou Kangdi Medical Products Co., Ltd.
Company Address	:	19 Hsuan Wai Road, Tianqu sub-district office, Decheng District, Dezhou, Shandong, China
Product Name and Brand	:	Disposable Surgical Mask (*Xinweikang*)
Model/specifications	:	17.5cmx9.5cm
Related Directives and Annex	:	Medical Devices Directive 93/42/EEC and Annex VII
Related Standards	:	EN ISO 13485:2016 EN 14683:2019
Examination Intent	:	*Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII*
Review result	:	*During the examination of the provided Technical Documentation (No.: KDMP-TCF-001, Revision: A/0, dated 2020-Mar-15), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.*
Valid From	:	03.11.2020
Valid Until	:	03.10.2025
Authorized Signer	:	Wallace X
Job Title	:	Certificate Manager
Date of Issue	:	2020-03-17

CE

Page 1/1

The CE Mark may only be used if all relevant and effective EC Directives are complied with

ZUOCE CERTIFICATION & TESTING CENTER *Email for certificate query: certificate@zuoce.org*
Room 809, Bulding 5, No.256 Lin Xia Road, Shanghai, China

28. Nimu certification service grouping 不是欧盟公告机构，证书无效。

CERTIFICATE

With EU Directive of 93/42/EEC Medical Device Directive(MDD)

Certificate No.:	NB0316YFCC200317-R09
Holder:	Yuanlong(Fujian)Commodity Co., Ltd Tanhuawang Industrial Area, Yongchun County, Quanzhou City, Fujian Province, China.
Product:	Disposable Protective Mask
Model(s):	YL01,YL02, YL03, YL04, YL05, YL06, YL07, YL08
Standards:	EN 14683:2005 EN ISO 14971:2012 EN ISO 15223-1:2016 EN 1041:2008 EN ISO 10993-1:2009

Based upon the voluntary assessment of the product sample and Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and EC directives.

The manufacturer has the responsibility for ensuring that all serial manufacture of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.

Date:17.03.2020

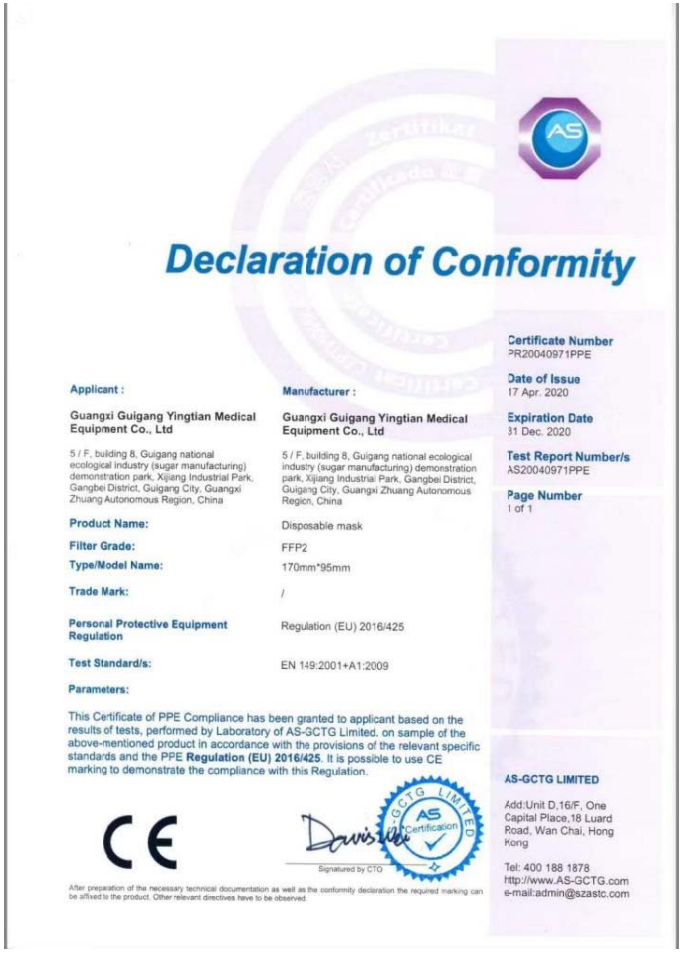
CE

Certification Body
For and on behalf of
NIMU (UK) CERTIFICATION SERVICES GROUP LIMITED
Authorized Signatory(ies)
NIMU (UK) certification

The CE marking may be used if all relevant and effective EC directives are complied with.

NIMU (UK) Certification Services Group Limited
Chase Business Centre 39/41 Chase Side,Southgate,London,England

29. AS 深圳一家测试机构，不是欧盟公告机构，证书无效。



Declaration of Conformity

Certificate Number
PR20040971PPE

Date of Issue
17 Apr. 2020

Expiration Date
31 Dec. 2020

Test Report Number/s
AS20040971PPE

Page Number
1 of 1

Applicant :

Guangxi Guigang Yingtian Medical Equipment Co., Ltd

5 / F, building 8, Guigang national ecological industry (sugar manufacturing) demonstration park, Xijiang Industrial Park, Gangbei District, Guigang City, Guangxi Zhuang Autonomous Region, China

Manufacturer :

Guangxi Guigang Yingtian Medical Equipment Co., Ltd

5 / F, building 8, Guigang national ecological industry (sugar manufacturing) demonstration park, Xijiang Industrial Park, Gangbei District, Guigang City, Guangxi Zhuang Autonomous Region, China

Product Name: Disposable mask

Filter Grade: FFP2

Type/Model Name: 170mm*95mm

Trade Mark: /

Personal Protective Equipment Regulation: Regulation (EU) 2016/425

Test Standard/s: EN 149:2001+A1:2009

Parameters:

This Certificate of PPE Compliance has been granted to applicant based on the results of tests, performed by Laboratory of AS-GCTG Limited, on sample of the above-mentioned product in accordance with the provisions of the relevant specific standards and the PPE **Regulation (EU) 2016/425**. It is possible to use CE marking to demonstrate the compliance with this Regulation.

CE

Signatured by CTO

After preparation of the necessary technical documentation as well as the conformity declaration the required marking can be affixed to the product. Other relevant directives have to be observed.

AS-GCTG LIMITED

Add:Unit D,16/F, One Capital Place,18 Luard Road, Wan Chai, Hong Kong

Tel: 400 188 1878
http://www.AS-GCTG.com
e-mail:admin@szastc.com

30. JCT TESTING 是深圳一家测试机构，不是欧盟公告机构，证书无效。

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Shen Zhen JCT Testing Technology Co., Ltd.
10th Floor, K1 Electric Mall, West Coast Complex, Jincheng Road, Shajing Street, Baoan District, Shenzhen, China

JCT TESTING

Certificate of Compliance

Certificate Number: JCT-2020040871E

Certificate's Holder : Zhangpu Tongbao Industry & Trade Co.,Ltd. Management Area of Field Department, Dananban Town, Zhangpu County, Zhangzhou City,Fujian Province

Manufacturer : Zhangpu Tongbao Industry & Trade Co.,Ltd. Management Area of Field Department, Dananban Town, Zhangpu County, Zhangzhou City,Fujian Province

Trade Mark : JCJZ

Product : Disposable Protective Mask

Model(s) : TB-01

Test Standard : EN 149: 2001+ A1: 2009

This Attestation of Compliance is issued on a voluntary basis for Medical apparatus and instruments product below the standard limits of PPE Directive (EU)2016/425. The essential requirement are fulfilled accordingly based on the technical specifications applicable at the time of issuance. See also notes overleaf.It is only valid in connection with the test report number: JCT-20200407220E

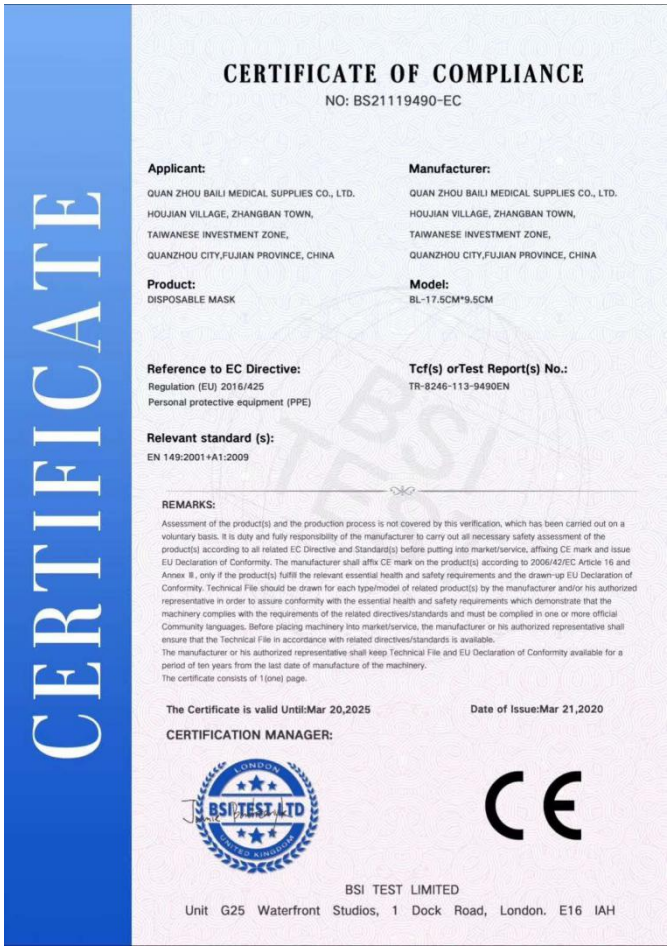
CE

Approved
Apr. 08, 2020

This Certificate of Conformity is based on single evaluation of the submitted sample(s) of the above menticned product. It does not imply an assessment of the whole product and relevant . Directives to be observed.

+0755 2306 2525 +86-755-2233 7722 http://www.jct-lab.com

31. BSI TEST LTD 不是欧盟公告机构，证书无效。



CERTIFICATE

CERTIFICATE OF COMPLIANCE

NO: BS21119490-EC

Applicant:
QUAN ZHOU BAILI MEDICAL SUPPLIES CO., LTD.
HOUJIAN VILLAGE, ZHANGBAN TOWN,
TAIWANESE INVESTMENT ZONE,
QUANZHOU CITY,FUJIAN PROVINCE, CHINA

Manufacturer:
QUAN ZHOU BAILI MEDICAL SUPPLIES CO., LTD.
HOUJIAN VILLAGE, ZHANGBAN TOWN,
TAIWANESE INVESTMENT ZONE,
QUANZHOU CITY,FUJIAN PROVINCE, CHINA

Product:
DISPOSABLE MASK

Model:
BL-17.5CM*9.5CM

Reference to EC Directive:
Regulation (EU) 2016/425
Personal protective equipment (PPE)

Tcf(s) orTest Report(s) No.:
TR-8246-113-9490EN

Relevant standard (s):
EN 149:2001+A1:2009

REMARKS:
Assessment of the product(s) and the production process is not covered by this verification, which has been carried out on a voluntary basis. It is duty and fully responsibility of the manufacturer to carry out all necessary safety assessment of the product(s) according to all related EC Directive and Standard(s) before putting into market/service, affixing CE mark and issue EU Declaration of Conformity. The manufacturer shall affix CE mark on the product(s) according to 2006/42/EC Article 16 and Annex II , only if the product(s) fulfill the relevant essential health and safety requirements and the drawn-up EU Declaration of Conformity. Technical File should be drawn for each type/model of related product(s) by the manufacturer and/or his authorized representative in order to assure conformity with the essential health and safety requirements which demonstrate that the machinery complies with the requirements of the related directives/standards and must be complied in one or more official Community languages. Before placing machinery into market/service, the manufacturer or his authorized representative shall ensure that the Technical File in accordance with related directives/standards is available.
The manufacturer or his authorized representative shall keep Technical File and EU Declaration of Conformity available for a period of ten years from the last date of manufacture of the machinery.
The certificate consists of 1(one) page.

The Certificate is valid Until:Mar 20,2025

Date of Issue:Mar 21,2020

CERTIFICATION MANAGER:

BSI TEST LTD

CE

BSI TEST LIMITED
Unit G25 Waterfront Studios, 1 Dock Road, London. E16 IAH

32. QCT 是广州一家测试机构，不是欧盟公告机构，证书无效。

CERTIFICATE OF COMPLIANCE

Certificate Number:QCT-D200310322
Medical devices Directive 93/42/EEC

QCT

Holder.....: Shouhang Jieneng (Quanzhou) Medical Technology Co., Ltd

Address.....: No. 1, Shanjiao , Zhuyuan Village, Meilin Street Office, Nan'an City, Quanzhou City, Fujian Province

Manufacturer.....: Shouhang Jieneng (Quanzhou) Medical Technology Co., Ltd

Address.....: No. 1, Shanjiao , Zhuyuan Village, Meilin Street Office, Nan'an City, Quanzhou City, Fujian Province

Product.....: Disposable Medical Mask

Trademark.....: YINGKANGNI

Model .....: Flat Ear Type、Flat Strap Type、Folding Ear Type

The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European standards

EN 14683:2019

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.

This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.

CE

Certification Manager
Date:Mar.18,2020

Guangzhou QCT Technology Testing Co., Ltd.
China :603 Chuangrong Cultural Center, No 36 Changsheng Street, Gangfeng Village, Yongning Sub-District, Zengcheng District, Guangzhou, China
Web:Http:www.qctjc.com FUJIAN BODA TEST TECHNOLOGY CO.,LTD

33. CCT 是深圳一家测试机构，不是欧盟公告机构，证书无效。

Certificate of Conformity

CERTIFICATE OF CONFORMITY

Certificate No.: CCT20032023ACS

Applicant.....: LIANYUNGANG MANAI PERSONNEL PROTECTION EQUIPMENT CO.,LTD.
No.18, jiguan Road, Jinshan Town, Ganyu District, Lianyungang City, Jiangsu Province, China

Manufacturer.....: LIANYUNGANG MANAI PERSONNEL PROTECTION EQUIPMENT CO.,LTD.
No.18, jiguan Road, Jinshan Town, Ganyu District, Lianyungang City, Jiangsu Province, China

Product.....: face mask
Trade Name.....: welooo
Type: FFP2 FACE MASK
Model(s) .....: KN95

It is only valid in connection with the test report number **CCT20032023ARS** Identification of regulation/standards.

EN 149: 2001+A1:2009

The EUT described above has been tested by us with the listed standards and found in compliance with the council **PPE Directive 2016/425/EU**. It is possible to use CE marking to demonstrate the compliance with this PPE Directive.

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole production and other relevant directives have to be observed.

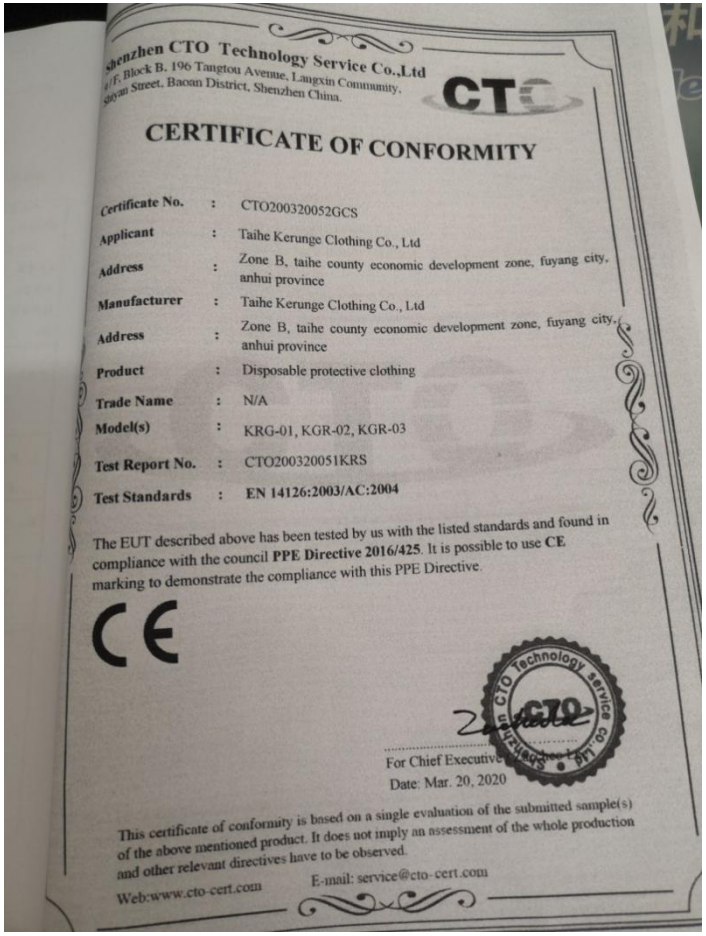
CE

Toby/Senior Manager
Mar. 20, 2020

CCT Testing Service

Shenzhen CCT Testing Technology Co., Ltd.
8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Yulv Community, Guangming New District, Shenzhen, Guangdong, China
Web: www.cct-prc.com Tel: 400-8788-298 Fax: 0755-33609691 Email: cct@cct-prc.com

34. 这是深圳一家测试机构，冒充欧盟公告机构 CTC，证书无效。



Shenzhen CTO Technology Service Co.,Ltd
4/F, Block B, 196 Tangtou Avenue, Langxin Community, Shiyan Street, Baoan District, Shenzhen China.

CERTIFICATE OF CONFORMITY

Certificate No.	:	CTO200320052GCS
Applicant	:	Taihe Kerunge Clothing Co., Ltd
Address	:	Zone B, taihe county economic development zone, fuyang city, anhui province
Manufacturer	:	Taihe Kerunge Clothing Co., Ltd
Address	:	Zone B, taihe county economic development zone, fuyang city, anhui province
Product	:	Disposable protective clothing
Trade Name	:	N/A
Model(s)	:	KRG-01, KGR-02, KGR-03
Test Report No.	:	CTO200320051KRS
Test Standards	:	EN 14126:2003/AC:2004

The EUT described above has been tested by us with the listed standards and found in compliance with the council **PPE Directive 2016/425**. It is possible to use **CE** marking to demonstrate the compliance with this PPE Directive.

CE

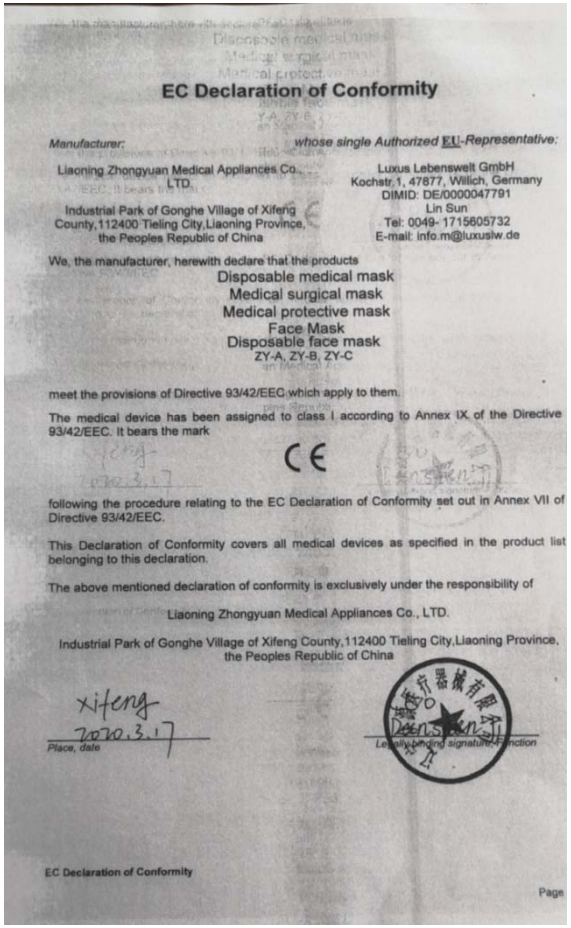
For Chief Executive
Date: Mar. 20, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole production and other relevant directives have to be observed.

Web:www.cto-cert.com E-mail: service@cto-cert.com

四、有效证书示例

1.这是一份企业自我声明书



EC Declaration of Conformity

Manufacturer:

Liaoning Zhongyuan Medical Appliances Co., LTD.

Industrial Park of Gonghe Village of Xifeng County,112400 Tieling City,Liaoning Province, the Peoples Republic of China

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable medical mask
Medical surgical mask
Medical protective mask
Face Mask
Disposable face mask
ZY-A, ZY-B, ZY-C

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Liaoning Zhongyuan Medical Appliances Co., LTD.

Industrial Park of Gonghe Village of Xifeng County,112400 Tieling City,Liaoning Province, the Peoples Republic of China

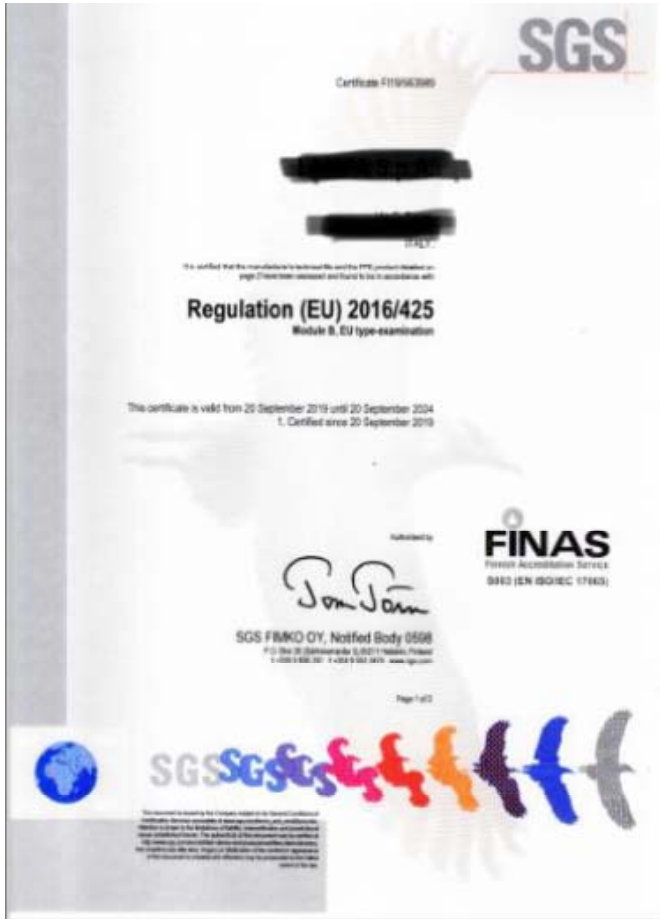
xifeng
2020.3.17
Place, date

Legally binding signature / function

EC Declaration of Conformity

Page

2. 通标标准技术服务有限公司证书样本



SGS

Certificate [redacted]

Regulation (EU) 2016/425

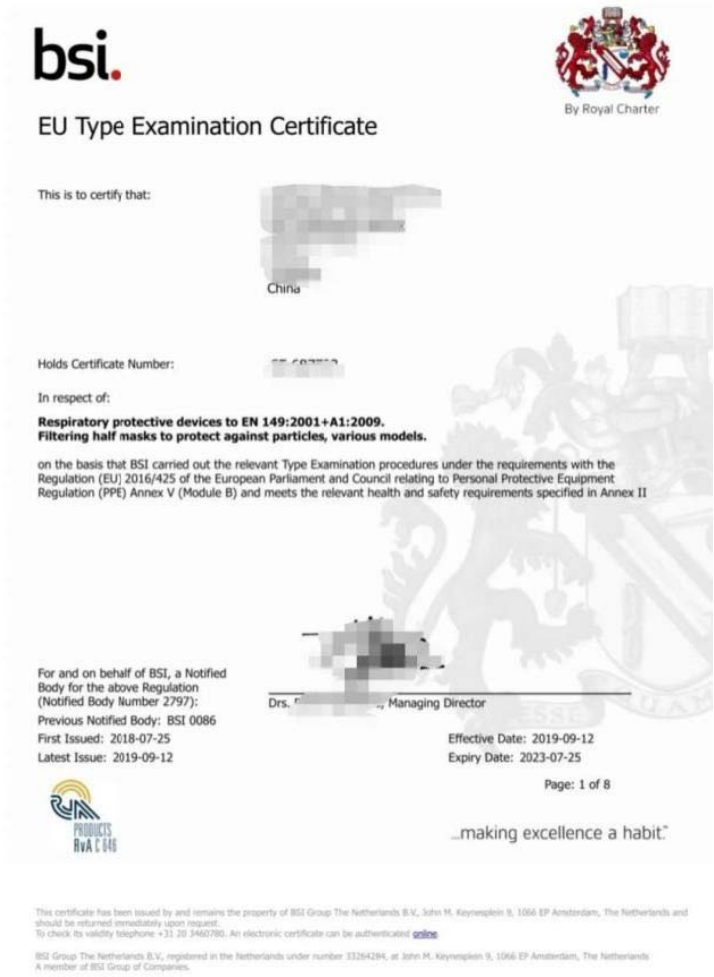
Module B, EU type-examination

This certificate is valid from 25 September 2019 until 20 September 2024
1. Certified since 20 September 2019

FINAS

SGS FIMKO OY, Notified Body 0598

3.英标管理体系认证(北京）有限公司证书样本



bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

[redacted]

China

Holds Certificate Number: [redacted]

In respect of:

Respiratory protective devices to EN 149:2001+A1:2009.
Filtering half masks to protect against particles, various models.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

[redacted], Managing Director

Previous Notified Body: BSI 0086

First Issued: 2018-07-25

Effective Date: 2019-09-12

Latest Issue: 2019-09-12

Expiry Date: 2023-07-25

Page: 1 of 8

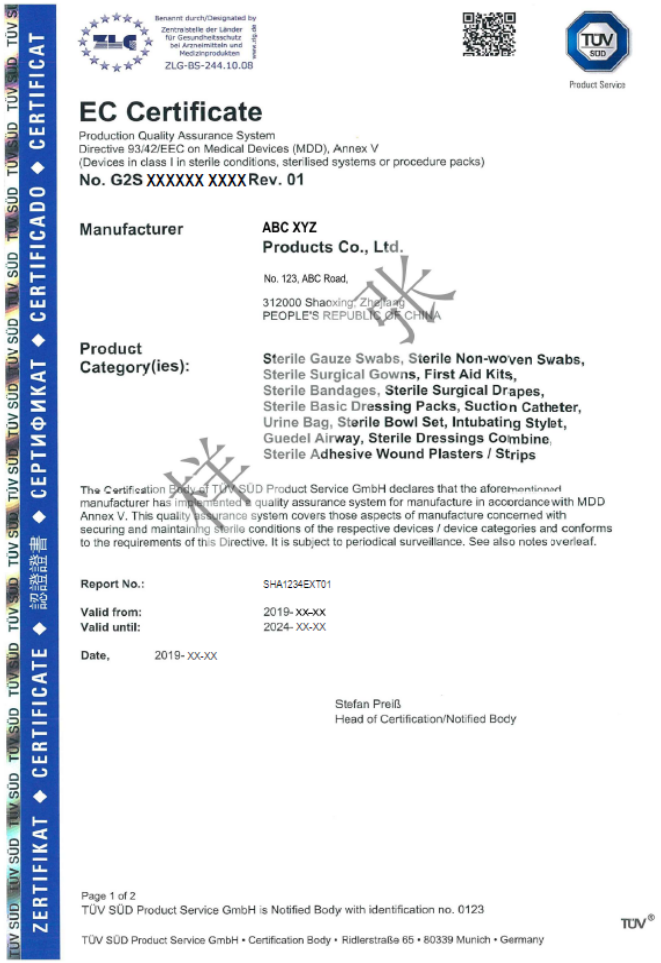
PRODUCTS RvA C 646

„making excellence a habit."

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

4. 南德认证检测（中国）有限公司（TÜV SÜD Product Service GmbH Zertifizierstellen



TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S XXXXXX XXXX Rev. 01

Manufacturer

ABC XYZ
Products Co., Ltd.
No. 123, ABC Road,
312000 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile Gauze Swabs, Sterile Non-woven Swabs, Sterile Surgical Gowns, First Aid Kits, Sterile Bandages, Sterile Surgical Drapes, Sterile Basic Dressing Packs, Suction Catheter, Urine Bag, Sterile Bowl Set, Intubating Stylet, Guedel Airway, Sterile Dressings Combine, Sterile Adhesive Wound Plasters / Strips

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SHA1234EXT01

Valid from: 2019-XX-XX
Valid until: 2024-XX-XX

Date, 2019-XX-XX

Stefan Preiß
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC 证书

生产质量保证体系
医疗器械指令 93/42/EEC (MDD)，附录 V
（I 类无菌器械，无菌组合包类产品）

二维码，可扫描查询证书信息
2019 年前颁发的证书二维码位置可能不同，或未使用二维码

No. G2S XXXXXX XXXX Rev. XX

证书号，I 类无菌产品证书号通常以 G2S 开头
2019 年前颁发的证书证书号形式为：
G2S XX XX XXXXX XXX

制造商　　名称

地址

产品类别　　证书覆盖的产品类别名称

同一张医疗器械 CE 指令证书可以包含不同种类的产品，例如：口罩（mask 或 face mask）、防护服（coverall）等

TÜV SÜD Product Service GmbH 的认证机构声明上述制造商已按照符合医疗器械指令附录 V 实施了生产质量保证体系。该质量保证体系覆盖与确保及保持有关设备/设备类别的无菌状态相关的各个制造环节并符合该指令要求。质量保证体系需要接受定期监督。参见背面说明。

报告号:　　XXXXXXXXXXX

有效期自:　　20XX-XX-XX

有效期至:　　20XX-XX-XX

日期　　20XX-XX-XX

认证机构/公告机构负责人（签名）

TÜV SÜD Product Service GmbH 是公告机构，公告号 0123
TÜV SÜD Product Service GmbH · 认证机构 · Ridlerstraße 65 · 慕尼黑 · 德国

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S XXXXXX XXXX Rev. 01

Facility(ies):

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